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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,894	12/03/2003	Todd Campbell	P1278 US	9611

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,894	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) 10-17 and 21-31 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 and 18-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10-14-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Response to Election/Restriction requirement, filed 5/16/2006 is acknowledged. Applicant elected Group I, claims 1 – 9 and 18 – 20.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 – 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed does not describe the FKBP 12 binding compounds as recited in claims 19 and 20. Not even one such compound is specifically identified. As such, the artisan would doubt that Applicant actually had possession of the coating as claimed with such compounds as the active agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, 18 – 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 recite the limitation "the surface" in claim 7. There is insufficient antecedent basis for this limitation in the claim. Further, it is unclear how a surface can be both a matrix and a mesh: For the purposes of compact prosecution, the claim will be interpreted to require a mesh upon which the polymer matrix is disposed. Clarification is requested.

Claim 18 recites "including but not limited to" a group of materials. If the subject matter of the claim is not limiting, then the claim cannot be said to distinctly claim the invention, since it is not clear what subject matter defines the metes and bounds of the claim.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,717,030 to Dunn et al., in view of US 5,510,188 to Bosch et al., of record.

Dunn teaches an implantable device coated with a polymer matrix coating (abstract). The polymer must be biodegradable, but the exemplary polymers (col. 7,

lines 7 – 21) include bioresorbable polymers such as poly lactides and non-bioresorbable polymers such as polycarbonates and poly(methyl vinyl) ethers. The polymer matrix is porous, reading on the requirement of claim 5 that it have a plurality of openings (col. 3, lines 56 – 54). The pores function to control the rate of release of the active agent. The coating is disposed on a wound dressing, such as a mesh (col. 4, lines 34 – 41), which is implantable. The drug is dispersed in the matrix in the form of nanoparticles (claim 6).

Dunn does not teach the size of the nanoparticles. Also, Dunn teaches neither matrix openings (pores) of uniform size, nor the details regarding the uniformity of the mesh.

Bosch teaches drug nanoparticles that are between 10 nm and 500 nm in diameter, and methods of making the same (abstract, claims 1 – 3). These nanoparticles can be manufactured from any drug (col. 4, line 54 – col. 5, line 42). The advantages associated with the nanoparticles of Bosch include remarkably high bioavailability of the drug (col. 4, lines 11 – 12).

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the nanoparticles of Bosch in the invention of Dunn. The motivation to do so comes from Bosch, who teaches that the nanoparticles provide high bioavailability of the drug. Since Dunn calls for nanoparticulate drugs, the artisan would enjoy a reasonable expectation of success. Further, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to vary the size of the pores or the mesh in depending on the intended use of the device. With regard to

the pores, Dunn teaches that the pores control the release rate of the active agent. Thus, uniformity of pore sizes would give rise to a predictable release profile, which the artisan would be motivated take advantage of to best treat the condition of interest. With regard to the mesh, the mesh of Dunn is used for wound healing, for example, and so the mesh-size or uniformity thereof would depend on the size and dimensions of the wound to be treated. The artisan would choose the appropriate mesh depending on the wound being treated, and would have a reasonable expectation of success.

Claims 2 and 18 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,717,030 to Dunn et al., and US 5,510,188 to Bosch et al., of record as applied to claim 1, 3 – 9, above, and further in view of US US 6,517,858 to Le Moel et al.

The teachings of Dunn and Bosch are discussed above.

What is lacking is a teaching of the drug of instant claims.

Le Moel teaches the inclusion of rapamycin in an implant (claim 10) in order to prevent restinosis (abstract). Rapamycin is a FKBP 12 binding macrolide antibiotic.

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use rapamycin as the drug in the invention of Dunn and Bosch. The motivation to do so is to prevent restinosis. Since this drug is known to be compatible with implantable devices, the artisan would enjoy a reasonable expectation of success.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Luo et al. "Rapamycin resistance tied to defective regulation of p27" in Molecular and Cellular Biology, Dec. 1996 is relied on for the teaching that rapamycin is a macrolide abtibiotic that binds to FKBP 12.

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1615

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